





# Guidelines for Vaccinating Pregnant Women

from Recommendations of the Advisory Committee on Immunization Practices (ACIP)

October 1998 (Updated May 2007)

### **Vaccination of Pregnant Women**

Risk for a developing fetus from vaccination of the mother during pregnancy primarily is theoretical. No evidence exists of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids. Live vaccines pose a theoretical risk to the fetus. Benefits of vaccinating pregnant women usually outweigh potential risks when the likelihood of disease exposure is high, when infection would pose a risk to the mother or fetus, and when the vaccine is unlikely to cause harm."

Generally, live-virus vaccines are contraindicated for pregnant women because of the theoretical risk of transmission of the vaccine virus to the fetus. If a live-virus vaccine is inadvertently given to a pregnant woman, or if a woman becomes pregnant within 4 weeks after vaccination, she should be counseled about the potential effects on the fetus. But vaccination is not ordinarily an indication to terminate the pregnancy.

Whether live or inactivated vaccines are used, vaccination of pregnant women should be considered on the basis of risks versus benefits – i.e., the risk of the vaccination versus the benefits of protection in a particular circumstance. The following table may be used as a general guide.

VACCINE		SHOULD BE CONSIDERED IF OTHERWISE INDICATED	CONTRAINDICATED DURING PREGNANCY	SPECIAL/CONDITIONAL RECOMMENDATION (SEE TEXT)	
	Hepatitis A			(See page 1)	
	Hepatitis B	Х			
	Human Papillomavirus (HPV)			(See page 1)	
	Influenza (Inactivated)	Recommended			
	Influenza (LAIV)*		Х		
ш	Measles*		Х		
	Meningococcal (MCV4)			(See page 2)	
ROUTINE	Mumps*		Х		
	Pneumococcal			(See page 2)	
	Polio (IPV)			(See page 2)	
	Rubella*		Х		
	Tetanus-Diphtheria (Td)	Х			
	Tetanus-Diphtheria-Pertussis (Tdap)			(See page 4)	
	Varicella*		Х		
TRAVEL & OTHER	Anthrax			(See page 5)	
	BCG*		Х		
	Japanese Encephalitis			(See page 5)	
	Meningococcal (MPSV4)	Х			
	Rabies	Х			
	Typhoid (Parenteral & Oral*)			(See page 5)	
	Vaccinia*		Х	(See page 5)	
	Yellow Fever*			(See page 6)	
	Zoster*		Х		

<sup>\*</sup>Live attenuated vaccine

### **Passive Immunization during Pregnancy**

"No known risk exists for the fetus from passive immunization of pregnant women with immune globulin preparations."

## Guidelines for Vaccinating Pregnant Women

Abstracted from recommendations of the Advisory Committee on Immunization Practices (ACIP)

Hepatitis A	Н	е	pa	at	į.	ti	S	F	1
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• The safety of hepatitis A vaccination during pregnancy has not been determined; however, because hepatitis A vaccine is produced from inactivated [hepatitis A virus], the theoretical risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in pregnant women who may be at high risk for exposure to [hepatitis A virus].<sup>2</sup>

### Hepatitis B

- Pregnancy is not a contraindication to vaccination.

  Limited data indicate no apparent risk for adverse events to developing fetuses when hepatitis B vaccine is administered to pregnant women. Current vaccines contain noninfectious HBsAg and should cause no risk to the fetus.<sup>3</sup>
- Pregnant women who are identified as being at risk for HBV infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STD, recent or current injection drug use, or having had an HBsAg-positive sex partner) should be vaccinated.<sup>3</sup>

# Human Papillomavirus (HPV)

- Quadrivalent HPV vaccine is not recommended for use in pregnancy.<sup>4</sup>
- The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination during pregnancy are limited. Until additional information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, no intervention is needed.<sup>4</sup>
- A vaccine in pregnancy registry has been established; patients and health-care providers should report any exposure to . . . HPV vaccine during pregnancy (telephone: 800-986-8999).4

### Influenza (Inactivated)

- Vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for severe complications from influenza: . . . Women who will be pregnant during the influenza season.<sup>5</sup>
- One study of influenza immunization of approximately 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine; similar results were observed in a study of 252 pregnant women who received inactivated influenza vaccine within 6 months of delivery.<sup>5</sup>

### Influenza (LAIV) Persons who should not be vaccinated with LAIV . . . pregnant women. . . . These persons should receive inactivated influenza vaccine.5 Measles-mumps-rubella (MMR) vaccine and its component Measles vaccines should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines.6 If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.<sup>1</sup> Meningococcal (MCV4) MCV4 is safe and immunogenic among nonpregnant persons aged 11-55 years, but no data are available on the safety of MCV4 during (conjugate) pregnancy. Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their health-care provider or the vaccine manufacturer. Mumps Measles-mumps-rubella (MMR) vaccine and its component vaccines should not be administered to women known to be **pregnant**. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines.6 If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.1 Pneumococcal The safety of pneumococcal polysaccharide vaccine during the first trimester of pregnancy has not been evaluated, although no adverse (PPV23) consequences have been reported among newborns whose mothers (polysaccharide) were inadvertently vaccinated during pregnancy.8 Polio (IPV) Although no adverse effects of IPV have been documented among pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. However, if a pregnant woman is at increased risk for infection and requires immediate protection against polio, IPV can be administered in accordance with

the recommended schedules for adults.9

#### Rubella

- Measles-mumps-rubella (MMR) vaccine and its component vaccines should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines.<sup>6</sup>
- If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR... vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR... vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.<sup>1</sup>
- Rubella-susceptible women who are not vaccinated because they state they are or may be pregnant should be counseled about the potential risk for CRS and the importance of being vaccinated as soon as they are no longer pregnant.<sup>10</sup>
- A registry of susceptible women vaccinated with rubella vaccine between 3 months before and 3 months after conception the "Vaccine in Pregnancy (VIP) Registry" was kept between 1971 and 1989. No evidence of CRS occurred in the offspring of the 226 women who received the current RA 27/3 rubella vaccine and continued their pregnancy to term.<sup>10</sup>

# Tetanus & Diphtheria (Td) (See also Tdap)

- Pregnant women should receive Td vaccine if indicated. Previously vaccinated pregnant women who have not received a Td vaccination within the last 10 years should receive a booster dose.<sup>1</sup>
- Pregnant women who have not received three doses of a vaccine containing tetanus and diphtheria toxoids should complete a series of 3 vaccinations. Two doses of Td should be administered during pregnancy to ensure protection against maternal and neonatal tetanus. The preferred schedule in pregnant women is two doses of Td separated by 4 weeks, and a dose of Tdap 6 months after the second dose (post-partum). Health-care providers can choose to substitute a single dose of Tdap for a dose of Td during pregnancy.<sup>11</sup>
- Although no evidence exists that tetanus and diphtheria toxoids are teratogenic, waiting until the second trimester of pregnancy to administer Td is a reasonable precaution for minimizing any concern about the theoretical possibility of such reactions.<sup>12</sup>

# Tetanus, Diphtheria, & Pertussis (Tdap)

- Pregnancy is not a contraindication for use of Tdap. Data on safety, immunogenicity and the outcomes of pregnancy are not available for pregnant women who receive Tdap. When Tdap is administered during pregnancy, transplacental maternal antibodies might protect the infant against pertussis in early life. They also could interfere with the infant's immune response to infant doses of DTaP, and leave the infant less well protected against pertussis.<sup>11</sup>
- ACIP recommends Td when tetanus and diphtheria protection is required during pregnancy. In some situations\*, health-care providers can choose to administer Tdap instead of Td to add protection against pertussis. When Td or Tdap is administered during pregnancy, the second or third trimester is preferred.<sup>11</sup>
- Providers who choose to administer Tdap to pregnant women should discuss the lack of data with the pregnant women and are encouraged to report Tdap administrations regardless of the trimester, to the appropriate manufacturer's pregnancy registry: for Boostrix® to GlaxoSmithKline Biologicals at 1-888-825-5249, or for Adacel®, to sanofi pasteur at 800-822-2463.<sup>11</sup>
  - \* "Situations with increased risk for pertussis: Health-care providers can choose to administer Tdap instead of Td to protect against pertussis in pregnant adolescents for routine or "catch-up" vaccination because the incidence of pertussis is high among adolescents, in pregnant health-care personnel and child care providers to prevent transmission to infants younger than 12 months of age and to other vulnerable persons, and in pregnant women employed in an institution or living in a community with increased pertussis activity."

#### Varicella

- The effects of the varicella virus vaccine on the fetus are unknown; therefore, **pregnant women should not be vaccinated.**Nonpregnant women who are vaccinated should avoid becoming pregnant for 1 month following each injection. For susceptible persons, having a pregnant household member is not a contraindication to vaccination.<sup>13</sup>
- Because the virulence of the attenuated virus used in the vaccine is less than that of the wild-type virus, the risk to the fetus, if any, should be even lower.<sup>13</sup>
- If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after . . . varicella vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, . . . varicella vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.<sup>1</sup>
- VZIG [Varicella Zoster Immune Globulin] should be strongly considered for susceptible, pregnant women who have been exposed.<sup>13</sup>
- NOTE: The manufacturer and CDC have established a Varivax® Pregnancy Registry to monitor outcomes of women who received the vaccine 3 months before or any time during pregnancy. Call 800-986-8999.

Anthrax	<ul> <li>No studies have been published regarding use of anthrax vaccine among pregnant women. Pregnant women should be vaccinated against anthrax only if the potential benefits of vaccination outweigh the potential risks to the fetus.<sup>14</sup></li> </ul>
BCG	• Although no harmful effects to the fetus have been associated with BCG vaccine, its use is not recommended during pregnancy. <sup>15</sup>
Japanese Encephalitis	<ul> <li>No specific information is available on the safety of JE vaccine in pregnancy. Vaccination poses an unknown but theoretical risk to the developing fetus, and the vaccine should not be routinely admin- istered during pregnancy.<sup>16</sup></li> </ul>
	<ul> <li>Pregnant women who must travel to an area where risk of JE is high should be vaccinated when the theoretical risks of immunization are outweighed by the risk of infection to the mother and developing fetus.<sup>16</sup></li> </ul>
Meningococcal (MPSV4) (polysaccharide)	• Studies of vaccination with MPSV4 during pregnancy have not documented adverse effects among either pregnant women or newborns. On the basis of these data, pregnancy should not preclude vaccination with MPSV4, if indicated. <sup>7</sup>
Rabies	<ul> <li>Because of the potential consequences of inadequately treated rabies exposure, and because there is no indication that fetal abnormalities have been associated with rabies vaccination, pregnancy is not con- sidered a contraindication to postexposure prophylaxis.<sup>17</sup></li> </ul>
	• If the risk of exposure to rabies is substantial, preexposure prophylaxis might also be indicated during pregnancy. <sup>17</sup>
Typhoid	• No data have been reported on the use of any of the three typhoid vaccines among pregnant women. <sup>18</sup>
Vaccinia (Smallpox)	• Live-viral vaccines are contraindicated during pregnancy; therefore, vaccinia vaccine should not be administered to pregnant women for routine nonemergency indications. <sup>19</sup>
	<ul> <li>However, vaccinia vaccine is not known to cause congenital malformations. Although &lt;50 cases of fetal vaccinia infection have been reported, vaccinia virus has been reported to cause fetal infection on rare occasions, almost always after primary vaccination of the mother.<sup>19</sup></li> </ul>
	<ul> <li>Pregnant women who have had a definite exposure to smallpox virus (i.e., face-to-face, household, or close-proximity contact with a smallpox patient) and are, therefore, at high risk for contracting the disease, should be vaccinated.         Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women. Therefore the risks to the mother and fetus from experiencing clinical smallpox substantially outweigh any potential risks regarding vaccination. In addition, vaccinia virus has not been documented to be teratogenic, and the incidence of fetal vaccinia is low.     </li> <li>When the level of exposure risk is undetermined, the decision to vacci-</li> </ul>
	nate should be made after assessment by the clinician and the patient of the potential risks versus the benefits of smallpox vaccination. <sup>19</sup>

#### Yellow Fever

- The safety of yellow fever vaccination during pregnancy has not been established, and the vaccine should be administered only if travel to an endemic area is unavoidable and if an increased risk for exposure exists.<sup>20</sup>
- ... infection of the fetus with YF17D apparently occurs at a low rate ... and has not been associated with congenital anomalies.<sup>20</sup>
- If international travel requirements are the only reason to vaccinate a pregnant woman, rather than an increased risk of infection, efforts should be made to obtain a waiver letter from the traveler's physician.<sup>20</sup>
- Pregnant women who must travel to areas where the risk of yellow fever is high should be vaccinated and, despite the apparent safety of this vaccine, infants born to these women should be monitored closely for evidence of congenital infection and other possible adverse effects resulting from yellow fever vaccination.<sup>20</sup>
- If vaccination of a pregnant woman is deemed necessary, serologic testing to document an immune response to the vaccine can be considered, because the seroconversion rate for pregnant women in a developing nation has been reported to be substantially lower than that observed for other healthy adults and children. To discuss the need for serologic testing, the appropriate state health department or the Division of Vector-Borne Infectious Diseases (telephone: 970-221-6400) or the Division of Global Migration and Quarantine (telephone: 404-498-1600) at CDC should be contacted.<sup>20</sup>

### Zoster (Shingles)

The ACIP has not yet issued recommendations on zoster vaccine. The manufacturer recommends not administering the vaccine during pregnancy:

- Contraindications: Zostavax should not be administered to individuals . . . who are or may be pregnant.<sup>21</sup>
- It is . . . not known whether Zostavax can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, naturally occurring VZV infection is known to sometimes cause fetal harm. Therefore, Zostavax should not be administered to pregnant females; furthermore, pregnancy should be avoided for three months following vaccination.<sup>21</sup>

### **Prenatal Serologic Screening**

The ACIP currently recommends prenatal screening for rubella and hepatitis B:

**Rubella:** "Prenatal serologic screening... is indicated for all pregnant women who lack acceptable evidence of rubella immunity. Upon completion or termination of their pregnancies, women who do not have serologic evidence of rubella immunity or documentation of rubella vaccination should be vaccinated with MMR before discharge from the hospital, birthing center, or abortion clinic." <sup>10</sup>

Hepatitis B: "All pregnant women should be routinely tested for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested." "Women who are HBsAg positive should be referred to an appropriate case-management program to ensure that their infants receive timely postexposure prophylaxis and followup." "Women who are HBsAg positive should be provided with or referred for appropriate counseling and medical management." "When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine ≤12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to HBsAg-positive mothers." For more information, see Reference 3, p. 13.

### **Vaccinating Women Who Are Breastfeeding**

"Neither inactivated nor live vaccines administered to a lactating woman affect the safety of breast-feeding for mothers or infants. Breast-feeding does not adversely affect immunization and is not a contraindication for any vaccine, with the exception of smallpox vaccine."

The following applies to varicella vaccine, which was licensed after the ACIP General Recommendations were published: "Whether attenuated vaccine VZV is excreted in human milk and, if so, whether the infant could be infected are not known. Most live vaccines have not been demonstrated to be secreted in breast milk. Attenuated rubella vaccine virus has been detected in breast milk but has produced only asymptomatic infection in the nursing infant. Therefore, varicella vaccine may be considered for a nursing mother." <sup>13</sup>

### References

- 1. CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006; 55 (No. RR-15): 32-33.
- 2. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006; 55 (No. RR-7): 15.
- 3. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) part 1: immunization of infants, children, and adolescents. MMWR 2005; 54 (No. RR-16): 12, 14.
- 4. CDC. Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007; 56 (No. RR-2): 18.
- 5. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2006; 55 (No. RR-10): 11-12.
- 6. CDC. Notice to readers: revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (No. 49): 1117.
- 7. CDC. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005; 54 (No. RR-7): 15.
- 8. CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997; 46 (No. RR-8): 6.
- 9. CDC. Poliomyelitis prevention in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2000; 49 (No. RR-5): 14.
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- 11. CDC. Prevention of tetanus, diphtheria and pertussis among pregnant women: provisional ACIP recommendations for the use of Tdap vaccine, 2006. Available at http://www.cdc.gov/nip/recs/provisional\_recs/tdap-preg.pdf.
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- 13. CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996; 45 (No. RR-11): 19-20.
- 14. CDC. Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000; 49 (No. RR-15): 11.
- 15. CDC. The role of BCG vaccine in the prevention and control of tuberculosis in the United States: a joint statement by the Advisory Council for the Elimination of Tuberculosis and the Advisory Committee on Immunization Practices. *MMWR* 1996; 45 (No. RR-4): 13.
- 16. CDC. Inactivated Japanese encephalitis vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1993; 42 (No. RR-1): 12-13.
- 17. CDC. Human rabies prevention–United States, 1999: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1999; 48 (No. RR-1): 17.
- 18. CDC. Typhoid immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1994; 43 (No. RR-14): 7.

- 19. CDC. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2001; 50 (No. RR-10): 12 & 19.
- 20. CDC. Yellow fever vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2002. *MMWR* 2002; 51 (No. RR-17): 7.
- 21. Zostavax (Package Insert). Whitehouse Station, NJ: Merck & Co. Inc.; 2006. Available at http://www.merck.com/product/usa/pi circulars/z/zostavax/zostavax pi.pdf.

#### For More Information

More detailed information about vaccination of pregnant women can be found in:

- ACIP statements for specific diseases.
- The ACIP's Update on Adult Immunization (*MMWR* Vol. 40, No. RR-12, November 15, 1991). See especially p. 9 and Appendix 5, pp. 82-88.
  - Current ACIP recommendations can be found on the National Immunization Program's website at http://www.cdc.gov/nip/publications/ACIP-list.htm. Or call the National Immunization Program's Information Center at (404) 639-8226.
- The American College of Obstetricians and Gynecologists (ACOG) **Technical Bulletin Number 160**, October 1991. This publication is available from the American College of Obstetricians and Gynecologists, Attn: Resource Center, 409 12th Street SW, Washington, DC 20024-2188.
- The American College of Physicians' *Guide for Adult Immunization*, Third Edition, pp. 25-29. Customer Service for the American College of Physicians can be contacted at (215) 351-2600 or (800) 523-1546.